



UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES
BOX INTERFERENCE, WASHINGTON, D.C. 20231

MAILED

Filed by: Fred E. McKELVEY
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JAN 30 2002

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Patentees: Stice, et al.
Patent: 5,945,577, granted 08/31/99, based
on Application 08/781,752, filed 01/10/97
For: Cloning using donor nuclei from
proliferating Somatic Cells

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 104,746.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

mck

FRED E. McKELVEY
Senior Administrative Patent Judge

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper 1

Filed by: Fred E. McKelvey
Senior Administrative Patent Judge
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

Filed
30 January 2002

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

JAN 30 2002

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

STEVEN L. STICE, JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 5,945,577),

v.

KEITH HENRY STOCKMAN CAMPBELL and IAN WILMUT,

Senior Party
(Application 09/650,194).

Patent Interference 104,746 (McK)

NOTICE DECLARING INTERFERENCE
(37 CFR § 1.611)

Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties.

Details of the application, patent, counts and claims designated as corresponding or as not corresponding to the counts appear in Parts E and F of this NOTICE DECLARING INTERFERENCE.

Part B. Judge designated to handle the interference

Senior Administrative Patent Judge Fred E. McKelvey has been designated to handle the interference. 37 CFR § 1.610(a).

Part C. Standing order

A Trial Section STANDING ORDER accompanies this NOTICE DECLARING INTERFERENCE. The STANDING ORDER applies to this interference.

Part D. Conference call to set dates

A telephone conference call to set dates for taking action in the interference is scheduled for 1:30 p.m. (1330 hours Eastern Time) on 13 March 2002 (the call will be initiated from the PTO).

No later than 8 March 2002, each party shall file and serve by facsimile a list of the preliminary motions the party intends to file. See § 17 of the STANDING ORDER.

A copy of a "sample" order setting times for taking action during the preliminary motion phase of the interference accompanies this NOTICE DECLARING INTERFERENCE.

Counsel are encouraged to discuss the order prior to the conference call with the view to coming to some mutual agreement as to dates for taking action. A typical preliminary motion period lasts approximately nine (9) months. Counsel should be prepared to justify any request for a shorter or longer period.

Part E. The parties involved in this interference are:

Junior Party

Named inventors: Steven L. Stice, MA
Jose Cibelli, MA
James Robl, MA
Paul Golueke, MA
F. Abel Ponce de Leon, MA
D. Joseph Jerry, MA

Patent: U.S. Patent 5,945,577,¹
granted 31 August 1999,
based on application 08/781,752,
filed 10 January 1997

Title: Cloning using donor nuclei from
proliferating somatic cells

Assignee: University of Massachusetts

Accorded Benefit: None

Attorneys: See last page

Address: See last page

¹ Maintenance fee not yet due.

Senior Party

Named Inventors: Keith Henry Stockman Campbell, UK
Ian Wilmut, UK

Application: Application 09/650,194,
filed 29 August 2000

Title: Unactivated oocytes as cytoplasm
recipients for nuclear transfer

Assignee: Roslin Institute (Edinburgh), The
Minister of Agriculture, Fisheries &
Food and Biotechnology & Biological
Sciences Research Council

Accorded Benefit:² Application 08/803,165,
filed 19 February 1997,
now U.S. Patent 6,252,133,
granted 26 June 2001

PCT application PCT/GB96/02098,
filed 30 August 1996

Attorneys: See last page

Address: See last page

² Campbell also claims the benefit under 35 U.S.C. § 119 of UK patent application 95-17779, filed 31 August 1995. Since there are differences between the disclosure of (1) the UK patent application and (2) the involved Campbell application, Campbell parent application 08/803,165 and the PCT application, benefit for the purpose of priority is not accorded at this time. During the preliminary motion period, Campbell may move for benefit for the purpose of priority. 37 CFR § 1.633(f).

Part F. Count and claims of the parties

Count 1

A method according to any of claims 1, 2, 3, 4, 5 or 6 of Stice patent 5,945,577, where the "non-human mammal" is a cow or a bovine and where the "non-human mammalian fetus" is a cow fetus or a bovine fetus,

or

a method according to any of claims 19 or 23 of Campbell application 08/803,165.

The claims of the parties are:

Stice: 1-24

Campbell: 19-50

The claims of the parties which correspond to Count 1, and therefore are involved in the interference (35 U.S.C. § 135(a)), are:

Stice: 1-24

Campbell: 19-26 and 35-50

The claims of the parties which do not correspond to Count 1, and therefore are not involved in the interference as to Count 1, are:

Stice: None

Campbell: 27-34

50-2

Count 2

A method according to any of claims 1, 2, 3, 4, 5 or 6 of Stice patent 5,945,577, where the "non-human mammal" is a sheep or an ovine and where the "non-human mammalian fetus" is a sheep fetus or an ovine fetus,

or

a method according to any of claims 27 or 31 of Campbell application 08/803,165.

The claims of the parties are:

Stice: 1-24

Campbell: 19-50

The claims of the parties which correspond to Count 2, and therefore are involved in the interference (35 U.S.C. § 135(a)), are:

Stice: 1-22

Campbell: 27-50

The claims of the parties which do not correspond to Count 2, and therefore are not involved in the interference as to Count 2, are:

Stice: 23-24

Campbell: 19-26

Count 3

A method according to any of claims 1, 2, 3, 4, 5 or 6 of Stice patent 5,945,577, where the "non-human mammal" is a pig or a porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus,

or

a method according to any of claims 35 or 39 or 43 or 47 of Campbell application 08/803,165, where the "non-human mammal" is a pig or a porcine and where the "non-human mammalian fetus" is a pig fetus or a porcine fetus.

The claims of the parties are:

Stice: 1-24

Campbell: 19-50

The claims of the parties which correspond to Count 3, and therefore are involved in the interference (35 U.S.C. § 135(a)), are:

Stice: 1-22

Campbell: 35-50

The claims of the parties which do not correspond to Count 3, and therefore are not involved in the interference as to Count 3, are:

Stice: 23-24

Campbell: 19-34

Part G. Heading to be used on papers

The following heading shall be used on papers filed in the interference. See § 18 of the STANDING ORDER.

Paper ³

Filed on behalf of [name of party]
By: Name of lead counsel, Esq.
Name of backup counsel, Esq.
Street address
City, State, and Zip-Code
Tel:
Fax:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

STEVEN L. STICE, JOSE CIBELLI, JAMES ROBL,
PAUL GOLUEKE, F. ABEL PONCE de LEON
and D. JOSEPH JERRY,

Junior Party,
(Patent 5,945,577),

v.

KEITH HENRY STOCKMAN CAMPBELL and IAN WILMUT,

Senior Party
(Application 09/650,194).

Patent Interference 104,746 (McK)

TITLE OF PAPER

³ Leave a blank line because the board assigns the paper number.

Part H. Summary of dates for taking action

Times for taking action are set out in the following sections of the STANDING ORDER:

1. **§ 7:** date for identifying lead and backup counsel.
2. **§ 8:** date for identifying any real party in interest.
3. **§ 9:** date for requesting copies of involved and benefit applications and patents.
4. **§ 17:** date for filing list of proposed preliminary motions.
5. **§ 19:** date for accomplishing certain discovery.
6. **§ 20:** date for filing clean copy of claims.
7. **§ 21:** date for filing clean copy of claims in cases with drawings and/or claims containing a means plus function limitation.
8. **§ 23:** dates for filing oppositions to Rule 635 miscellaneous motions and dates for filing replies to oppositions.
9. **§ 33:** date for objecting to admissibility of evidence.
10. **§ 34:** date for serving supplemental affidavits or evidence to respond to objection to admissibility of evidence.
11. **§ 35:** dates when cross-examination can take place.
12. **§ 45:** dates for taking action with respect to settlement discussions

Part I. Order form for requesting file copies

FILE COPY REQUEST

Interference 104,746 (McK)

A copy of Part E of this NOTICE DECLARING INTERFERENCE should be attached to this FILE COPY REQUEST, with a circle by hand around the patents and applications for which a copy of a file wrapper is desired.

To facilitate processing of this FILE COPY REQUEST, the following information should be included:

1. Charge fees to USPTO Deposit Account No. _____
2. Complete address, including street, city, state, zip code and telephone number (do not list a Post Office box inasmuch as file copies are sent via commercial overnight courier).

Telephone, including area code: _____

Part J. Signature of administrative patent judge

mck

Fred E. McKelvey
Senior Administrative Patent Judge

30 January 2002
Arlington, VA

Enc:

Copy of STANDING ORDER

Copy of order used for setting times for taking action in
the preliminary motion phase of the interference (ORDERPM6)

Copy of order used for setting times for taking action in
the testimony and briefing phases of the interference
(ORDERTE6)

There is no PTO Form 850

Copy U.S. Patents:

5,945,577
6,252,133
6,235,696
6,215,041

Copy of Campbell claims 19-50

Campbell REQUEST UNDER 37 C.F.R. § 1.607 FOR INTERFERENCE
WITH U.S. PATENT 5,945,577 TO STICE ET AL. (without
attachments)

Bibliographic data for the involved application and patent

DECLARE.007
Revised September, 2000
(replaces DECLARE.006.1)

104,746

cc (via Federal Express) :

Attorney for Stice
(real party in interest
University of Massachusetts) :

PILLSBURY WINTHROP LLP
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1600 Tysons Boulevard
McLean, VA 22102

Tel: None
Fax: None
E-mail: None

Attorney for Campbell
(real party in interest
Roslin Institute (Edinburgh),
The Minister of Agriculture, Fisheries & Food and
Biotechnology & Biological Sciences Research Council) :

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103. An improved method of cloning a non-human mammal by nuclear transfer comprising the introduction of a non-human mammalian donor cell or a non-human mammalian donor cell nucleus into a non-human mammalian enucleated oocyte of the same species as the donor cell or donor cell nucleus to form a nuclear transfer (NT) unit, implantation of the NT unit into the uterus of a surrogate mother of said species, and permitting the NT unit to develop into the cloned mammal, wherein the improvement comprises using as the donor cell or donor cell nucleus a proliferating somatic cell that has been expanded in culture, or a nucleus isolated from said somatic cell.

Serial No.08/781,752
Art Unit 1632

Proposed Claims

103. An improved method of cloning a non-human mammal by nuclear transfer comprising the introduction of a non-human mammalian donor cell or a non-human mammalian donor cell nucleus into a non-human mammalian enucleated oocyte of the same species as the donor cell or donor cell nucleus to form a nuclear transfer (NT) unit, implantation of the NT unit into the uterus of a surrogate mother of said species, and permitting the NT unit to develop into the cloned mammal, wherein the improvement comprises using as the donor cell or donor cell nucleus a somatic cell isolated from a continuously growing culture of said cell, or nucleus isolated from said somatic cell.

*note a)
somatic
cell
prolif.
said
cell
culture*

*proliferating culture comprising proliferating non-human
mammalian somatic cells
that has been expanded in culture*

104. An improved method of cloning a non-human mammal by nuclear transfer comprising the introduction of a non-human mammalian donor cell or a non-human mammalian donor cell nucleus into a non-human mammalian enucleated oocyte of the same species as the donor cell or donor cell nucleus to form a nuclear transfer (NT) unit, implantation of the NT unit into the uterus of a surrogate mother of said species, and permitting the NT unit to develop into the cloned mammal, wherein the improvement comprises using as the donor cell or donor cell nucleus a somatic cell isolated from a continuously growing culture of said cells, or nucleus isolated from said somatic cell and wherein the donor cell or donor cell nucleus has been genetically transformed to comprises at least one addition, substitution or deletion nucleic acid sequence.

105. A method of cloning a non-human mammal by nuclear transfer comprising the following steps:

(i) inserting a desired non-human mammalian somatic cell isolated from a continuous growing culture of said somatic cells, or a nucleus isolated therefrom into a non-human mammalian enucleated oocyte of the same species under conditions suitable for the

Proposed Claims

formation of a nuclear transfer (NT) unit;

(ii) activating the resultant nuclear transfer unit;

(iii) culturing said activated NT unit until greater than the 2-cell developmental stage;

and

(iv) transferring said cultured NT unit to a host non-human mammal of the same species such that the NT develops in to a non-human mammal.

106. An improved method of cloning a non-human mammalian fetus by nuclear transfer comprising the introduction of a non-human mammalian donor cell or a non-human mammalian donor cell nucleus into a non-human mammalian enucleated oocyte of the same species as the donor cell or donor cell nucleus to form a nuclear transfer (NT) unit, implantation of the NT unit into the uterus of a surrogate mother of the same species, and permitting the NT unit to develop into the mammalian fetus, wherein the improvement comprises using as the donor cell or donor cell nucleus a somatic cell isolated from a continuously growing culture of said cell, or nucleus isolated from said somatic cell.

107. An improved method of cloning a non-human mammalian fetus by nuclear transfer comprising the introduction of a non-human mammalian donor cell or a non-human mammalian donor cell nucleus into a non-human mammalian enucleated oocyte of the same species as the donor cell or donor cell nucleus to form a nuclear transfer (NT) unit, implantation of the NT unit into the uterus of a surrogate mother of the same species, and permitting the NT unit to develop into the mammalian fetus, wherein the improvement comprises using as the donor cell or donor cell nucleus a somatic cell isolated from a continuously growing culture of said cells, or nucleus isolated from said somatic cell and wherein the donor cell or donor cell nucleus has been genetically transformed to comprises at

Proposed Claims

least one addition, substitution or deletion nucleic acid sequence.

108. A method of cloning a non-human mammalian fetus by nuclear transfer comprising the following steps:

- (i) inserting a desired non-human mammalian somatic cell isolated from a continuously growing culture of said cells, or a nucleus isolated therefrom into a non-human mammalian enucleated oocyte of the same species under conditions suitable for the formation of a nuclear transfer (NT) unit;
- (ii) activating the resultant nuclear transfer unit;
- (iii) culturing said activated NT unit until greater than the 2-cell developmental stage; and
- (iv) transferring said cultured NT unit to a host non-human mammal of the same species such that the NT develops into a fetus.

109. The method of claim ^{any one of} 106,107 or 108, wherein the fetus develops into an offspring.

110. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from mesoderm.

111. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from endoderm.

112. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from ectoderm.

Proposed Claims

113. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from a fibroblast.

114. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from an ungulate.

115. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from an ungulate selected from the group consisting of bovine, ovin, porcine, equine, caprine and buffalo.

116. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from a non-human mammalian fetus.

117. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from an adult non-human mammalian cell.

118. The method of claims 103-108, wherein the donor cell or donor cell nucleus is selected from the group consisting of epithelial cells, neural cells, epidermal cells, keratinocytes, hematopoietic cells, melanocytes, chondrocytes, B-lymphocytes, T-lymphocytes, erythrocytes, amcrophages, monocytes, fibroblasts, muscle cells, and nuclei isolated therefrom.

119. The method of claims 103-108, wherein the donor cell or donor cell nucleus is from an organ selected from the group consisting of skin, lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney and urethra.

Proposed Claims

120. The method of claims 103-108, wherein the oocyte is matured in vitro or in vivo prior to enucleation.

121. The method of claims 103-108, wherein the oocyte is matured in vitro prior to enucleation.

122. The method of claims 103-108, wherein the oocyte is enucleated by micro-surgical methods.

123. The method of claims 103-108, wherein the oocyte is enucleated about 10 to 40 hours after initiation of in vitro maturation.

124. The method of claims 103-108, wherein the oocyte is matured in vivo prior to enucleation.

125. The method of claims 103-105, wherein the non-human mammal is bovine.

126. The method of claims 106-108, wherein the non-human mammal is bovine.

INTERFERENCE DIGEST

Interference No. 104,746

Paper No. 24

Name: Steven L. Stice, et al.

Serial No.: 08/781,752

Patent No. 5,945,577

Title: Cloning using donor nuclei from proliferating somatic cells

Filed: 01/10/97 granted 08/31/99

Interference with Keith Henry Stockman Campbell, et al.

DECISION ON MOTIONS

Administrative Patent Judge, _____ Dated, _____

FINAL DECISION

Board of Patent Appeals and Interferences, Adverse Dated, 12/20/04

Court, _____ Dated, _____

REMARKS

This should be placed in each application or patent involved in interference in addition to the interference letters.